



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2021-0624; FRL-10296-01-OCSP]

#### Tetraniliprole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of tetraniliprole in or on the grain, cereal, group 15, except rice; and grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn, and sweet corn. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0624, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Daniel Rosenblatt, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-2875; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at the <https://www.ecfr.gov/current/title-40>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0624 in the subject

line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0624, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of October 21, 2021 (86 FR 58239) (FRL-8792-04-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP #1F8930) by Bayer

CropScience LP, 800 N Lindbergh Blvd., St. Louis, MO 63167. The petition requested to establish tolerances in 40 CFR part 180 for residues of the insecticide, tetraniliprole [1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2*H*-tetrazol-2-yl]methyl]-1*H*-pyrazole-5-carboxamide], in or on Crop Group 15; cereal grains, except rice at 0.01 parts per million (ppm); and Crop Group 16; forage, fodder, and straw of cereal grains group, except field corn, popcorn, and sweet corn at 0.1 ppm. That document referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>. No comments were received in response to the notice of filing.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tetraniliprole including exposure resulting from

the tolerances established by this action. EPA's assessment of exposures and risks associated with tetraniliprole follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

On February 24, 2021, EPA published a tolerance rulemaking for tetraniliprole in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to tetraniliprole and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the February 24, 2021, rulemaking as described further in this rulemaking, as they remain unchanged.

#### *A. Toxicological Profile*

For a discussion of the Toxicological Profile of tetraniliprole, see Unit III.A. of the tetraniliprole tolerance rulemaking published in the *Federal Register* of February 24, 2021 (86 FR 11133) (FRL-10005-77).

#### *B. Toxicological Points of Departure/Levels of Concern*

Based on a thorough analysis of the toxicology database of tetraniliprole, the Agency has determined that a qualitative risk assessment is more appropriate for tetraniliprole than a quantitative risk assessment. For more details, please reference Unit III.B. of the February 24, 2021, rulemaking.

#### *C. Exposure Assessment*

There is potential for exposure to tetraniliprole via food and feed based on the proposed uses. However, no adverse effects were observed in the submitted toxicological studies for tetraniliprole regardless of the route of exposure. Thus, no quantitative dietary exposure assessments are needed for EPA to conclude with reasonable certainty that dietary exposures to tetraniliprole do not pose a significant human health risk.

*Drinking water and non-occupational exposures.* There are no residues of toxicological concern expected in drinking water from the use of tetraniliprole. Thus, no drinking water exposure assessments are needed for the Agency to conclude with reasonable certainty that drinking water exposures to tetraniliprole do not pose a significant human health risk.

Tetraniliprole is registered for use on golf course turf and sports fields that could result in residential post-application exposures. However, no adverse effects were observed in the submitted toxicological studies for tetraniliprole regardless of the route of exposure; therefore, a quantitative residential post-application exposure assessment was not conducted. Thus, no residential exposure assessments are needed for the Agency to conclude with reasonable certainty that residential exposures to tetraniliprole do not pose a significant human health risk.

*Cumulative exposure.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tetraniliprole and any other substances. Tetraniliprole does not also appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore,

EPA has not assumed that tetraniliprole has a common mechanism of toxicity with other substances.

#### *D. Safety Factor for Infants and Children*

EPA has not identified any toxicological endpoints of concern associated with any threshold effects and conducted a qualitative assessment. That qualitative assessment showed no risk of concern for infants and children and does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. EPA has also evaluated the available data and concluded that there are no residual uncertainties concerning the potential risks to infants and children that would impact its conclusions about threshold effects.

#### *E. Aggregate risks and determination of safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

No adverse effects were observed in the submitted toxicological studies at doses relevant to human health pesticide risk assessment for tetraniliprole regardless of the route of exposure. Effects observed in the data base (*e.g.*, decreased body weight) were both marginal, and only seen at doses not expected to occur daily or over an extended period.

Based on a lack of toxicity at exposure levels expected from approved application rates and an expectation that aggregate exposures to residues of tetraniliprole will not reach the levels required to cause any adverse effects, EPA concludes that there is a

reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tetraniliprole residues. More detailed information on this action can be found in the document titled “Tetraniliprole: Human Health Risk Assessment for Registration for Uses on Cereal Grains, Except Rice, Crop Group 15; and Forage, Fodder, and Straw of Cereal Grains Group, except Field Corn, Popcorn, and Sweet Corn Crop Group 16” in docket ID EPA-HQ-OPP-2021-0624.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 24, 2021, rulemaking.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no Codex MRLs for tetraniliprole on the commodities covered in this document.

#### **V. Conclusion**

Therefore, tolerances are established for residues of tetraniliprole in or on grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn and sweet corn at 0.1 ppm; and grain, cereal, group 15, except rice at 0.01 ppm. In addition, EPA is removing the tolerance for indirect or inadvertent residues of tetraniliprole in or on grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn and sweet corn at 0.1 ppm, which is no longer needed with the changes described above.

#### **VI. Statutory and Executive Order Reviews**



This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: December 7, 2022.

**Daniel Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Amend § 180.709 by:

a. In Table 1 to paragraph (a) adding in alphabetical order entries for “Grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn and sweet corn”; and “Grain, cereal, group 15, except rice”; and

b. In Table 2 to paragraph (d) by removing the entry “Grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn and sweet corn”.

The additions read as follows:

**§ 180.709 Tetraniliprole; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	* *
Grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn and sweet corn	0.1
Grain, cereal, group 15, except rice	0.01
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